FOCAL meditech

TOP

DYNAMIC ARM SUPPORT SYSTEM

User's manual

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INTRODUCTION

This is the USER'S MANUAL of the dynamic arm support system TOP (hereafter TOP), which can be mounted on a wheelchair, chair or table. TOP is manufactured and distributed by FOCAL Meditech, a company that specializes in the supply of high-end head and body support systems, feeding devices and custom-made products. This manual provides infor-

mation on the product, the purpose, how to use it and the consequences of using it. The goal of this information is to guarantee a longlasting, successful and effective use of the dynamic arm support. You will know what you can and can't expect of the dynamic arm support and it provides global information on how to adjust TOP as well as to what features need special attention when using TOP. In the back of the manual you'll find contact information of the supplier.

This manual also provides information on our HELP component. HELP (which, in Dutch, is short for 'High And Low Positioning') is a usually standard added component to TOP that makes it possible to add vertical movements. This information is only important for users of this extra component.

Please take the time to read this information well: Profound knowledge of this aid leads to a more efficient use and yields better results. It is recommended that this manual is also read by persons in your surroundings, for instance those that play a role in you day-to-day care!

FOR WHOM IS TOP?

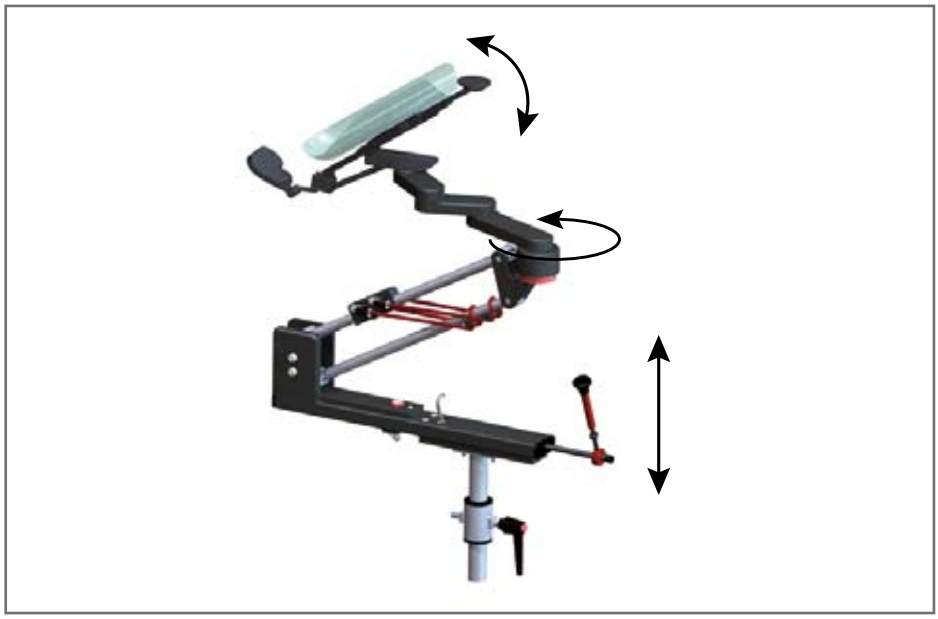
TOP was developed for all persons that can no longer position or use fore-arm and hand due to lack of muscle power or neulogical failure. To be able to use TOP, at least some functionality in shoulderbelt and upper-arm are required as well as some functionality of the hand (grab, manipulate). The arm support can also be used by healthy persons that often have burdening (job) positions. 'TOP' can be deployed both single-sided and double-sided. Single-sided or double-sided use depends on a range of factors, like the user's individual limitations and possibilities and his or her needs. the user of TOP can be active in a lot of different areas, i.e. at home, at school or in a job location, in an institution or any other location. TOP can also be used therapeutically, for instance by letting the user work with an increasing reach or with resistance. The HELP component, which is almost always delivered together with TOP, facilitates vertical arm displacements that allow a user to eat and drink independently or to reach high. This component is considered to be useful for most users.

Whether the dynamic arm support system is mounted on a wheelchair, chair or table also partly depends on the user's individual needs and wishes.

When reading the manual please pay special attention to the instructions concerning 'safe use'. Text that is of special interest for safety is marked with a safety symbol (see example).

WORKING PRINCIPLE OF TOP

The dynamic arm support system TOP is a system of axes with several rotation points, with an arm fitting and a connection with the 'real' world (chair, wheelchair, table or movable carriage). The fore-arm rests in the arm fitting allowing TOP to bear most of the weight of the user's arm and relieving the shoulder belt. Through the axes system TOP can aid conveying movements which are initiated in shoulders and upper-arm, to fore-arm and hands.



Dynamic arm support systems are mostly use by persons with limited muscle strength in shoulder belt or arms because of neurological or orthopaedic diseases in these parts of the body. By deploying what is left of the user's own capacities he or she can bring their hands to a 'useful' position. Reaching, grabbing and manipulating and therefore executing all kinds of daily activities are possible again. TOP operates mainly horizontally and is not extra fortified. The HELP component is usually delivered as part of TOP. This component, which is empowered mechanically by means of a spring mechanism, facilitates vertical displacements. Elektric empowering can be supplied.

TOP is characterized by a very rigid construction with a high-quality layering and with a minimal caprice in the different axes. It operates extremely light and smooth. This light operation together with a perfect fit and extensive adjustability asks little use of force by the user. TOP has more rotation points and more motion axes - even vertically - than any other known product. This makes its movements light and smooth. The system 'follows' the user's arm perfectly and the arm doesn't 'lock-up'. TOP is highly customisable and individual adjustments are made when needed.

The lockable version

For users who are in the need of a system that can be fixed in any given position a lockable version is available. Users can independently operate this function. The following are examples of situations where locking sometimes is desired: outdoor wheelchair driving; use during transfers.

Locking is performed by the use of a switch. This switch operates a an electric locking mechanism. Locking takes place in horizontal plane and can be realised in any given position. The locking mechanism is an optional feature and can be supplied for mechanical as well as electrically powered versions.

PARTS

DESCRIPTION

Description of the parts of the dynamic arm support system TOP, top-down.

- The arm fitting is located at the top of the system. The arm fitting is the part that holds the arm, it is always custom-made.

- At the front of the arm fitting a tilting handpalm support is usually found. This handpalm support is extensible and detachable. It's shape can be adjusted individually.

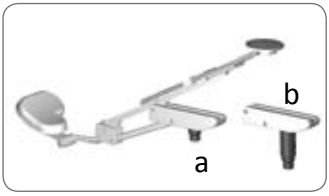
- Characteristic for the tilting version of TOP is that the arm fitting is mounted on a double joint, which makes tilting possible.

- The double joint is fitted with the so-called 'fitting shove' - a mechanism that is used to determine the tilting point of the arm fitting. This makes it possible to shift the arm fitting with respect to the double joint.

- The double joint is combined with the carriers of the before-mentioned handpalm support and the automatic elbow support.

- The purpose of the automatic elbow support is to prevent that the fore-arm slides out of the arm fitting when this is tilted upwards. The auto-matic elbow support can also be used to limit the tilting angle of the fore-arm.

- The so-called 'direct connecting rod' is located under the double joint. The direct connecting rod - a metal shaft that is put in a box with bearings - is located in the outer end of the exten-sion arm below it. The direct con-necting rod allows the arm fitting to rotate over the extension arm. A short (a) and a long (b) version of the direct connecting rod exist. When the short version is used, the arm fitting can rotate directly above the extension arm. When tilted the arm fit-ting could collide with the extension arm. When the long version is used this collision is prevented over a long tilting distance.



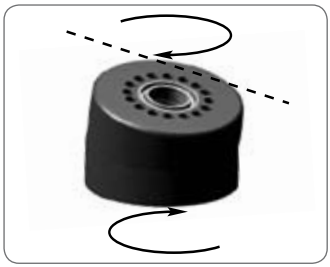
- Together with the arm fitting the extension arms provide the actual horizontal support of the fore-arm. The base version exi-sts of two short extension arms and one long one, which are respectively 70mm and 120mm long, but this can be changed according to the wishes of the user in order to create a maxi-mum reach. All joints of the exten-

sion arms exist of shafts and busses with bearings as described directly above).

- The rotation of the extension arms can be limited by means of a synthetic plug. This plug is put into the bottom of the extension arm close to the turning-point of the arm below. Also, one or two blocking pins can be put in small holes which are located around the center-hole in the bus below.

- The lower extension arm runs into the rotation block. The rotation block is a construction that exists of two circular discs that can be rotated in respect to each other. At the top it has a bus with bearings to which the extension arm is connected.

- Around the center-hole there's a pattern of smaller holes that allow limitation of rotation. The angle under which the upper components (for horizontal movement) operate can be adjusted by means of the rotation block. This is done bij changing the angle under which the arm support operates in respect to the user's body. This change can be made by turning the two discs - that have sloped edges - in respect to each other. Note: when adjusting the angle one should choose between the device's assistance in a certain direction



of movement and an optimal resting posture in which the user's arm falls back to the body automatically.

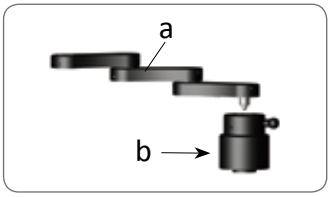
- At the bottom the rotation block is connected to a supporting structure: an adapter block that is mounted directly to the (wheel)chair or table. This adapter block is custom-made per application. If TOP has to operate vertically (with assistance of the HELP component), the rotation block is mounted on the HELP component.

DESCRIPTION – LOCKABLE VERSION

The following description only matters for TOP users that will use the lockable version. This version has an electromotor for the activation of a mechanical locking mechanism inside specific extension arms.

- External switch, light to operate. Can be positioned at any place near the user. Also switches of other brands can be applied.

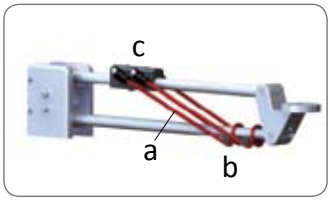
- Extension arms provided with a locking mechanism (a) (on the backside)
- Specific rotation block (b) with electric driving mechansim of the locking mechanism inside.



DESCRIPTION – MECHANICAL HELP COMPONENTS

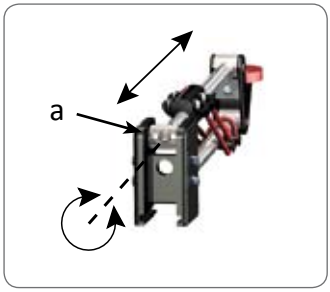
The following description only matters for TOP users that will also use the HELP component. This HELP component (in short: HELP) is the part that supports the fore-arm during vertical movements.

- HELP exists of two parallel tubes that are connected through joints (a parallellogram with variable proportions). The vertical displacement is assisted by two pre-wound elastic cords that

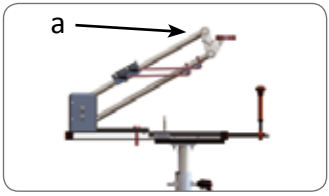


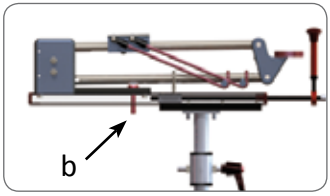
are connected to the two tubes. The cords (a) are tightly fit to the lower fixation point (b). The upper fixation point for the cords is located on a small adjustable block(c) on the upper tube.

- The position of the mounting block on the upper tube can be adjusted by means of a screw ax which is located in the upper tube (a). The mounting block is displaced when the screw ax at the back of the upper tube is turned - please use the provided hexagonal wrench. By displacing the mounting block it is possible to tighten or loosen the cords according to the user's wishes which respectively results in an increased or decreased support in upward movements. Be advised that increased support in upward movements automatically means that more pressure is required to move down again. On the opposite less support in the upward movement requires less pressure to move down again.

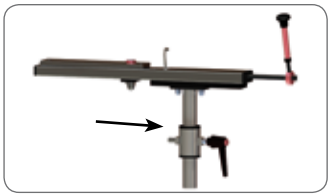


- HELP has an upper (a) and a lower (b) 'touchpoint'.

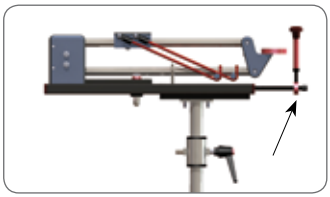




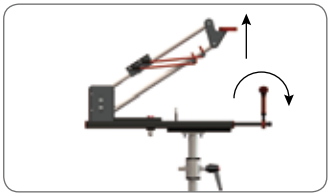
- TOP and HELP are located on a mounting tube. The mounting tube is, on one hand, the connection between TOP and HELP and on the other hand between the (wheel)chair or table.



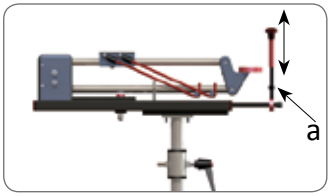
- The lever for blocking HELP in the lower position is located at the front of the mounting tube. Mechanical version only.



- This blocking mechanism is provided by a hook that is put over the lower tube. The lever makes it possible to attach and detach the hook.



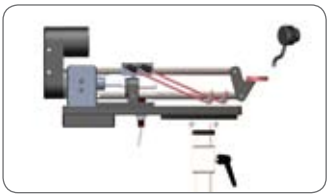
- To make operation of the lever easy and to prevent obstruction, the lever is made telescopically extensible. The position of the upper tube of the lever - when it is not extended - can be adjusted by means of an adjustment ring (a).



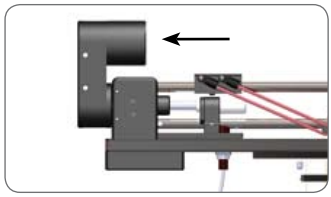
- Below the mounting tube is a specific adapter for mounting on a table, chair or wheelchair. This adapter is custom-made and offers possibilities for height adjustment.

DESCRIPTION – ELECTRIC HELP COMPONENTS

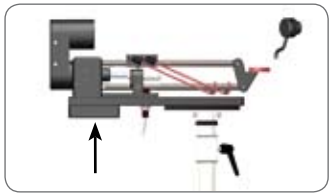
- If the up and down movements cannot be performed sufficiently, the HELP component can be fitted with elektronically fortified vertical displacement. An electromotor with accessories is fitted at the back of HELP. This electomotor is usually operated with a separate switch.



- Electromotor with cover and driving mechanism (mounted together)



- Switch unit with switch and fuse. The tuning of the upper stop is set electronically. In addition the supplier can alter the speed of the movements and the movement characteristics.



- Switch. The electronic HELP is commonly used by a separate switch that is very light to operate. Operation through a user interface integrated in the wheelchair operating system is however also possible. Also various other operating methods can be realised in consultation with the supplier.

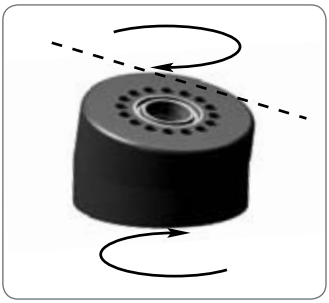
MOUNTING TOP

After a period of extensive try-out and evaluation, FOCAL Meditech mounts the dynamic arm support onto the support of choice. Mounting is individual and differs form person to person. Changing TOP to a new support or provision has to be done by FOCAL Meditech.

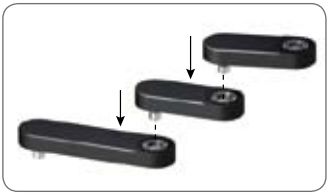
ADJUSTING TOP

Beware! Before adjusting TOP, all sitting elements of the (wheel) chair have to be put in the most common active sitting position.

1) Adjusting TOP requires before everything else that the perfect inclination angle for the system is determined. Use the provided hexagonal wrench to detach the two discs of the rotation block. The discs can now be turned by hand, put in the correct position and be attached again. When using the default position, the fore-arm has to turn slightly inwards later on. It may be needed to make some adjustments later.



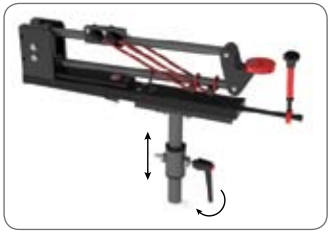
2) Mount the chosen extension arms by putting them together.
This avoids that the linear conductor moves in an area that is not desirable. The height of the system can now be adjusted by means of a button that is found at the lower end of the adjustment unit.



3) Mount the double-joint onto it.

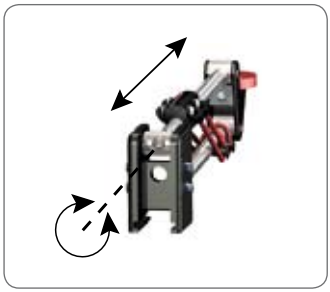
4) Put the user's arm in the arm fitting.

5) Determing the correct heigth adjustment by using the mounting adapter. Beware that the user's shoulders - when in a resting position - are horizontally lined up as much as possible. The user's comfort plays in important role here!



6) Ask the user to make some movements to get a little acquainted with TOP.

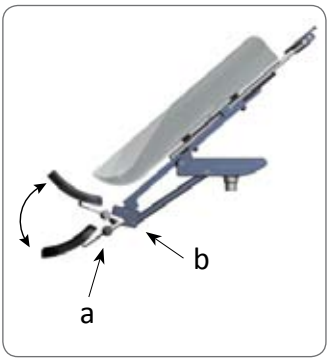
7) When using the HELP component: Try to level the weight of the arm as much as possible in order to compensate the downforce. In order to do so adjust the tension of the cords. Follow these steps: Ask the user to lift the arm and check if this can be done without dropping or that the user has problems lowering the arm again. Adjust the tension of the cords if needed: using the provided hexagonal wrench, turn the ax a few times to tighten or loosen the cords. Right rotation gives more assistance when lifting the arm while left rotation decreases assistance. Look at the effect, and adjust the tension a little more when needed. Turn the ax back a few rotations when lowering of the arm becomes 'heavy' .



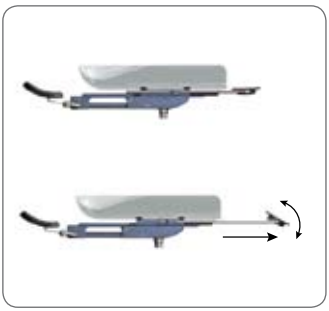
8) Position the swivel adjustment of the arm fitting. At the bottom of the arm fitting - between the two screws - a sunken bolt is located (a). This bolt fixates the shove plate, that is connected to the arm fitting, to the double joint. By moving the

shove plate, tilting the fore-arm will be easier. The more the arm fitting is moved backwards in respect to the joint the easier tilting the fore-arm upwards will be. At some point however it will become more difficult to tilt the arm back. It is advised that a good adjustment is made with the right balance between tilting up and down.

9) The automatic elbow support should be pressed against the lower part of the upper-arm when the fore-arm is tilted. Further adjust the effective angle of the support cushion through the bolt at the bottom of the cushion (a). The depth adjustment of the elbow support - i.e. the distance between support cushion and arm fitting - can be altered through the bolt that fixates the little bent rod (b) in the backside of the double joint.



10) The handpalm support can now be moved in such a way that the palm of the hand is supported in a comfortable way. The little cushion can either be left to tilt along with the hand or can be fixated under any chosen angle.



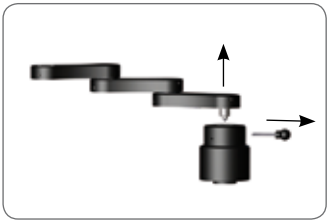
11) The horizontal movements of the extension arms can be limited if desired. This is done by putting a synthetic plug into the bottom of the extension arm. Blocking pins are then put in the pattern of holes of the underlying extension arm (or in the top of the rotation block), according to the area that has to be limited. Now, the extension arms can only rotate within the area that is confined by the pins. By limiting the rotation area of the extension arms, some improved functionality or therapeutic goals can be achieved - resp. avoiding a traject where the user can not operate well or activating muscle groups that would be insufficiently strained otherwise. However, the function of rotation limitation can also be avoiding contact between the tilted arm fitting and the extension arm.

12) Let the user try if the rotation limitation is correct and adjust the blocking pins if necessary.

USING TOP

How TOP is used depends on individual needs and wishes of the user and by the environment in which it is used. The activities that can be undertaken with the aid of the dynamic arm support 'TOP' are almost unlimited. Every Day Life activities consist mainly of eating and drinking independently as well as facial and dental care. Being able to reach one's head for putting on spectacles or a hearing aid are considered to be important too. Common activities are writing, using a computer, household activities, child care and nursing, playing and hobbies. However, even in such futile tasks as operating switches or daily used equipment, TOP is an indispensable asset.

The mechanism of the lockable version is switched on by moving the switch into the direction of the ‘X’ sign. The locking mechanism will actually lock when the user moves his arm slightly. The system is unlocked again when the switch is moved into the direction of the ‘O’ sign. If the armsupport ‘TOP” is provided with a locking mechanism the extension arms are indissolubly connected to the rotation block. To take the extension arms from the rotation block the locking pin must be removed.



The HELP component is integrated into most of the TOP arm support systems. HELP provides a means for vertical displacements of the arm in all kinds of activities.

Height adaptation of the electric version is performed by moving the switch into the direction of the ‘H’ (High) or the ‘L’(Low).

The dynamic arm support is often found mounted on a hand-operated or electric wheelchair and on working chairs alike. Especially in labour situations TOP will be mounted directlyto working tables. Users are

known to change their transport and sitting devices often. Of course it is possible to mount a dynamic arm support on every device a user has. To serve efficiency, the part that facilitates vertical displacement can be made interchangeable if this is technically and functionally possible. When the proper adjustments have been made the actual use is very simple.

The arm fitting can be provided with special accessories to allow the user to perform specific tasks like writing or eating. The dynamic arm support can also be used in combination with special hand splints.

WARNING

1) Never unlock the HELP component when not pressed upon, i.e. without an arm in it. If done so, the arm support will jump upwards and can harm persons or damage objects. When, for example in case of maintenance, HELP has to be unlocked without the user's arm in it, please make sure to fixate the moving part with your hand.

2) The arm support may never be used as support to lean on or to get upright. During evaluation it should be accounted for that the user sits stable and that it is possible for him or her to come into an upright position without leaning on the arm support.

MAINTENANCE

Not much maintenance is required for this dynamic arm support. The device can be cleaned with a moist cloth and a non-aggressive cleaning agent. Strong heating of the arm fitting, for instance by putting it on a central heating or in direct sunlight, should be avoided.

WARRANTY

MAIN

These warranty conditions are part of the Main Conditions of Delivery of FOCAL Meditech. When regarding the warranty conditions, the Main Conditions of Delivery should be taken under consideration.

The following warranty conditions are based on the EU Guideline 99/44/EG and the Act of Civil Law. The sale and application of medical appliances are further restricted by Guideline 93/42/EEG and the Royal Decision 243 of march 30th, 1995. Rights there stated are viable. Warranty conditions of seller towards end-user remain unchanged. Warranty periods and considerations can be extended or changed with written permission and considering what is agreed on in lawful guidelines.

Our products are manufactured and assembled with the greatest possible care. Still defects or breakdowns can occur. FOCAL Meditech will fix this on request, both during and beyond the warranty period. This guarantees that the product life span is not negatively influenced.

WARRANTY

We provide warranty according to the following conditions:

Article 1

Faults in the product that become evident within 24 months from the date of delivery to end-user are fixed without cost, with regard to conditions 2 through 14. When the product is used in a professional manner or use under similar conditions, the warranty period is limited to 12 months. For vintage products this period is also 12 months.

Article 2

Warranty means that the product is restored without charge to the non-defective state the product was in prior to the first occurance of the problem. FOCAL Meditech decides whether faulty parts are res-

tored or replaced. Parts that are replaced without charge remain property of FOCAL Meditech.

Article 3
Occurring problems should be reported immediately to avoid further damage. The right of warranty is cancelled when the problem is NOT reported within two months.

Article 4
To appeal for warranty, either the receipt in the name of the user should be presented or the proof of delivery in the name of the user - with date of purchase and/or delivery. If these are missing some other convincing evidence has to be presented..

Article 5
Warranty does NOT involve minor deviations of the standard quality, for instance (but not limited to) deviations in size or measurement that are insignificant for the value, validity or functionality of the product.

Article 6
Warranty does NOT involve damage resulting from careless or inconsiderate use or from use other than what the product was originally designed for.

Article 7
Warranty does also NOT involve damage caused by:

1) Chemical or electrochemical influences of water or other liquids.
2) Abnormal environmental conditions in general.
3) Improper conditions for use including unusual pressure conditions and acceleration.
4) Contact with aggressive agents.
5) Neglect.
6) Any other eternal cause, for instance bumping or collisions.

Article 8
Warranty does NOT involve malfunction because of damage sustained during transport and beyond the responsibility of FOCAL Meditech, unprofessional installation or montage, inadequate maintenance or disregarding maintenance guidelines..

Article 9
The right of warranty expires when a malfunction is the result of repair or interventions by third parties which are not qualified or skilled, or when the product was fitted with parts or accessories that are not original. The right of warranty also expires when (serial) numbers have been removed.

Article 10
Repair on the spot within 14 days is our goal. However, this can only be required in the case of a minor problem which is to be assessed by FOCAL Meditech. It can be necessary to transport the device to a workshop.

Article 11
If - during the warranty period - the repair of the same defect fails repeatedly, or when the costs of repair are in no comparison to the cure, an equal replacement is provided in consultation with the user. In case of replacement we reserve the right to charge a fee in accordance to the past period of use.

Article 12
Warranty repairs justify neither the extension of the current warranty period nor the start of a new warranty period except the part of the product that was repaired.
FOCAL Meditech provides a warranty period of 12 months on repairs, limited to the particular defect.

Article 13
Required or wanted repairs are not part of the standard product as documented in the manual. FOCAL Meditech will try to fix malfunc-

tions on individual adaptations according to the warranty for the standard product. Required or wanted individual repairs however are not part of the warranty conditions.

Article 14

Buyer's claims regarding warranty can not be transferred to other persons.

These warranty conditions apply to products that are bought and/or used in Holland. If a product is transferred abroad the user has to check whether the environmental conditions (i.e. electric current, climate conditions) coincide with the required conditions. The seller has to provide warranty when a product is sold again.

For FOCAL Meditech it is important that their products, which are mostly used by persons with severe limitations, function properly. We emphasize that defects or faulty/bad operation of the product due to causes that are NOT in the warranty conditions should always be reported.
Users can rely on our service facilities, even after regular warranty periods.

CE APPROVED

This product was CE approved and complies with European regulations for medical aids.

CONTACT INFORMATION

The dynamic arm support TOP and the HELP component are manufactured and delivered by

FOCAL Meditech BV
Droogdokkeneiland 19
5026SP Tilburg
The Netherlands.
Tel.: +31 13-533 31 03
Fax: +31 13-533 50 04
E-mail: info@focalmeditech.nl
Internet: www.focalmeditech.nl

FOCAL Meditech BV

Droogdokkeneiland 19

5026 SP Tilburg

Nederland

T +31 (0)13 533 31 03

F +31 (0)13 533 50 04

E info@focalmeditech.nl

I www.focalmeditech.nl